

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In Re Pharmaceutical Industry
Average Wholesale Price Litigation

This Document Relates To:
GOVERNMENT EMPLOYEES HOSPITAL
ASSOCIATION and DISTRICT COUNCIL
37 HEALTH AND SECURITY PLAN
TRUST, individually and on behalf of all
others similarly situated,

Plaintiffs

v.

SERONO INTERNATIONAL, S.A.,
SERONO LABORATORIES, INC.,
SERONO, INC., RJL SYSTEMS, INC., AND
RUDOLPH J. LIEDTKE,

Defendants.

MDL No. 1456

C.A. No. 05-cv-11935 (PBS)

PLAINTIFFS' MOTION TO REMOVE SPECIFIC ACTION FROM MDL

Pursuant to Local Rule 40(I), plaintiffs Government Employees Hospital Association and District Council 37 Health and Security Plan Trust respectfully requests that the specific action, *Government Employees Hospital Association, et al. v. Serono International, S.A., et al.*, C.A. No. 05-cv-11935 (PBS) (the “*Serono Action*”), currently consolidated with the AWP MDL, be unbundled from the AWP MDL and, if appropriate, reassigned. The claims in the *Serono Action* involve the use of unapproved and unproven body cell mass measurement devices to create a fraudulent basis for prescribing high priced drugs to AIDS victims, and the payment of kickbacks to prescribers in connection with the marketing of Serono products. The unlawful conduct alleged in the *Serono Action* is identical to unlawful conduct that resulted in a guilty plea

before the Hon. Reginald C. Lindsay by defendant Serono Laboratories, Inc. on December 15, 2005, and payment of restitution and fines in the amount of \$704 million to Medicaid. *United States v. Serono Laboratories, Inc.*, 05 CR 10282 RCL. The *Serono Action*, as initially pleaded, stated a claim based on AWP fraud, but the currently operative pleading, the Second Amended Class Action Complaint, filed on March 21, 2006, does not plead AWP fraud and, in fact, does not even contain the term “AWP.” Accordingly, plaintiffs respectfully recommend that the *Serono Action* be unbundled from the AWP MDL and returned to its initial status as a separate case.

Based on communications with counsel, plaintiffs understand that the Serono defendants do not oppose unbundling the *Serono Action* should from the AWP MDL, but wish to respond to plaintiffs’ motion to consider what further recommendation, if any, should be made to the Court.

FACTUAL BACKGROUND

This is a proposed national class action brought on behalf of consumers and third-party payors against Serono International, S.A., Serono, Inc., Serono Laboratories, Inc. (collectively “Serono”), RJL System, Inc. (“RJL”), and Rudolph J. Liedtke (“Liedtke”) seeking damages and other monetary relief for defendants’ deceptive and illegal promotional activities of the prescription AIDS drug Serostim and other pharmaceutical products. Specifically, the *Serono Action* alleges that Serono and other defendants marketed phony medical testing devices to falsely diagnose the condition of wasting in AIDS patients; paid inducements to providers that caused physicians to write prescriptions for Serostim; and caused consumers and third-party payors to pay for Serostim prescriptions – even though taking Serostim was medically unnecessary and of no medical benefit to the patient. The *Serono Action* also alleges that Serono paid illegal inducements, including unrestricted educational grants, stipends, travel benefits, and

other unlawful remuneration to physicians, physician groups, and hospitals, to increase the sales of Serostim and Serono's other drugs, and to reap unlawful profits at the expense of consumers and third-party payors.

On December 15, 2005, Serono Laboratories, Inc. pleaded guilty to federal criminal charges. A copy of the Felony Information in *United States v. Serono Laboratories, Inc.*, 05 CR 10282 RCL, filed October 17, 2005, is annexed hereto as Exhibit A. The \$704 million payment by Serono addressed the economic harm caused by defendants to the governmental third-party payor Medicaid. But it did not address the harm caused to consumers and non-governmental third-party payors. On December 15, 2005, Judge Lindsay, who presided over the criminal prosecution of Serono, observed at the plea and sentencing hearing (tr. 28-29):

I have in mind the scenario where there are . . . especially vulnerable victims who are people who have AIDS; and as I understand what has happened, what the government charges and what the corporation is planning to plead guilty to, is the selling of devices and medication to these victims with the promotion by the corporation that a symptom of their illness was wasting of the body; and that even in cases where they may not have had that symptom, they were led to believe that they did have that indication, that they were suffering, and they paid for the medication, they paid for the devices, which means to me that the person who pays . . . his or her co-insurance . . . can't [pay for] something else, other medication or pay the rent, pay the mortgage because it's going into the payment of -- for this device and this medication, which the patient had been led to believe is necessary for his health when it was not.

A copy of the transcript of Plea and Sentencing of Serono Laboratories, Inc. is annexed hereto as Exhibit B. The *Serono Action* is intended to address the harm caused by Serono's violations of the law to consumers and third-party payors, and the unjust enrichment to Serono that resulted.

PROCEDURAL BACKGROUND

Plaintiff Government Hospital Employees Association commenced the *Serono Action* with the filing of a complaint on September 23, 2005 against Serono International, Inc. and Serono, Inc. At the time the *Serono Action* was commenced, plaintiffs were informed and

believed that the tactics employed by the defendants resembled those used by the manufacturer in *In re Lupron* and, in consequence, stated a claim for AWP inflation. The Felony Information in the related criminal prosecution against Serono Laboratories, Inc., disclosing the details of Serono Laboratories fraudulent marketing scheme, had not yet been disclosed.

On October 24, 2005, Serono, Inc. filed a motion for reassignment of the *Serono Action* to this Court, and for consolidation with the AWP MDL. A copy of Serono, Inc.'s Memorandum in Support of its Motion for Reassignment Pursuant to Local Rule 40.1 is annexed hereto as Exhibit C. Two days later, October 26, 2005, this Court granted Serono, Inc.'s motion to transfer, and on October 31, 2005, seven days later, it granted the motion to consolidate. Because the motions were granted less than 14 days after they had been filed, plaintiff did not have an opportunity to respond. A copy of the docket sheet setting forth the orders is annexed hereto as Exhibit D.

On October 17, 2005, the United States Attorney's Office filed its Felony Information against Serono Laboratories, Inc., containing new material information concerning misconduct by defendants. As a result of this new information, on November 12, 2005, plaintiff filed its first amended complaint. The first amended complaint also added as defendants Serono Laboratories, Inc., RJL Systems, Inc., the medical device manufacturer with whom the Serono defendants conspired, and Rudolph J. Liedtke, the principal of RJL.

On December 15, 2005, Serono Laboratories, Inc. pleaded guilty. An extensive plea and sentencing hearing was held. In addition, the day before the hearing, the United States Attorney's Office filed the Government's Sentencing Memorandum. A copy of the Government's Sentencing Memorandum, dated December 14, 2005, is annexed hereto as Exhibit E. The plea and sentencing hearing and the Government's Sentencing Memorandum revealed

additional information material to plaintiff's claims. Thereafter, plaintiff's counsel obtained additional evidence supporting the allegation of widespread kickbacks paid by Serono to physicians, physician groups, and hospitals. In addition, plaintiff's counsel was retained by a third-party payor, District Council 37 Health & Security Plan Trust ("DC37 Plan"), which had paid millions of dollars in reimbursements for Serono products. Plaintiffs then prepared and filed, with defendants' consent and leave of the Court, their Second Amended Class Action Complaint on March 21, 2006. Defendants are scheduled to respond to the Second Amended Class Action Complaint on April 28, 2006.

THE SERONO ACTION SHOULD BE UNBUNDLED FROM THE MDL

The initial and first amended complaints in the *Serono Action* pleaded AWP fraud liability, but the factual basis of the complaint has always centered on the medical device and kickback schemes. These are precisely the unlawful acts that were identified by the United States Attorney in filing its Felony Information against Serono Laboratories, and the crimes concerning which Serono Laboratories pleaded guilty.

The Second Amended Complaint makes this clear. In 329 numbered paragraphs, and with 15 exhibits, the Second Amended Complaint articulates the misconduct engaged in by defendants. Much of the complaint is drawn from the criminal cases against Serono Laboratories and Serono employees. The Second Amended Complaint contains causes of action for RICO violations, civil conspiracy, c. 93A and other consumer protection statute violations, common law fraud, and unjust enrichment. It does not contain a single reference to AWP.

The *Serono Action* should be unbundled from the AWP MDL. There is no risk of inconsistent rulings between the *Serono Action* and the cases proceeding in the AWP MDL because there are no AWP issues in the *Serono Action*. Beyond that, consolidating the *Serono*

Action into the AWP MDL is prejudicial to the plaintiff and burdensome to the Court. The AWP MDL requires coordination with more than two dozen defendants, private class counsel, prosecuting state attorneys general and numerous prosecuting county attorneys. It is also well advanced, with motions for summary judgment as to the Track I defendants already scheduled. The *Serono Action*, on the other hand, entails a few related defendants, and no AWP fraud claims. No pretrial conference has been scheduled, no discovery has been undertaken. No defendant has answered the complaint. From a scheduling point of view alone, it makes no sense to have the *Serono Action* consolidated with the AWP MDL. There are no economies of scale. Keeping the *Serono Action* in the MDL will result only in confusion and delay.

REASSIGNMENT OF THIS ACTION

In the interest of justice and the efficient performance of the business of the Court, pursuant to Local Rule 40.1(I), plaintiff moves that the *Serono Action* be removed from the MDL. In addition, if the Court initially accepted the assignment of the *Serono Action* solely as a result of the presence of AWP allegations, the Court may wish to consider reassignment. In general, “[a]ssignment of related criminal and civil cases to a single judge will improve efficiency and coordination, especially when the cases are pending at the same time.” D. Herr, *Annotated Manual for Complex Litigation Fourth* (2004) § 10.123 at 20. In this case, there was a related criminal action, *United States v. Serono Laboratories, Inc.*, 05 CR 10282 RCL. While that action is no longer pending, the teaching of the *Manual for Complex Litigation* may still obtain. In addition, plaintiffs advise the Court of the following additional criminal cases pending in this Court involving the individuals, businesses, events, and transactions present in the *Serono Action*:

- *United States v. Adam Stupak*, 04 CR 10367 DPW (criminal prosecution of Serono sales director; guilty plea entered, awaiting sentencing).

- *United States v. John Bruens, Mary Stewart, Melissa Vaughn, and Marc Sirockman*, 05 CR 10102 JLT (criminal prosecution of Serono vice presidents and sales directors; awaiting trial).
- *United States v. RJL Systems, Inc. and Rudolph J. Liedtke*, 05 CR 10088 EFH (criminal prosecution of RJL and Liedtke; guilty pleas entered, awaiting sentencing).

Plaintiffs also note, in addition, that if the case is simply unbundled from the AWP MDL, it will remain with Judge Saris under current case no. C.A. No. 05-cv-11935 (PBS).

Plaintiff is available to assist the Court with additional information concerning these matters if it so desires.

WHEREFORE, for the foregoing reasons, plaintiffs respectfully request that this motion be granted.

REQUEST FOR ORAL ARGUMENT

Pursuant to L.R. 7.1(D), plaintiff respectfully submits that oral argument may assist the Court and wishes to be heard.

Respectfully submitted,

By /s/ David S. Nalven

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Dated: April 6, 2006

CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Docket No. MDL 1456

I hereby certify that I have conferred and attempted in good faith to narrow the issues with opposing counsel set forth herein. Specifically, on or about February 14, 2006, I provided a draft of the annexed motion to counsel for Serono International, S.A., Serono Laboratories, Inc., and Serono, Inc., and had several follow up discussions with counsel concerning the matter, including as recently as April 5, 2006. Defendants are now in agreement that the *Serono Action* should be unbundled from the AWP MDL, but wish to consider what further recommendation, if any, should be made to the Court, and to submit their own memorandum accordingly.

/s/ David S. Nalven

Dated: April 6, 2006

CERTIFICATE OF SERVICE

Docket No. MDL 1456

I, David S. Nalven, hereby certify that I am one of plaintiffs' attorneys and that, on April 6, 2006, I caused copies of the papers annexed hereto to be served on all counsel of record in this proceeding via Lexis/Nexis File Serve.

/s/ David S. Nalven

Dated: April 6, 2006